

Serial No.: 10/577,054
Atty. Docket No.: P71223US0

REMARKS

The Office Action mailed January 21, 2009, has been carefully reviewed and by this Amendment, claims 12 and 13 have been canceled, claim 7 has been amended, and new claims 21 and 22 have been added. Claims 1-11 and 14-22 are pending. Claims 1, 7 and 9 are independent. Claims 1-6, 9 and 11 have been withdrawn.

The Examiner objected to the drawings as containing informalities. Applicants have provided replacements sheets setting forth drawings in conformity with 37 C.F.R. 1.84(l) and indicating Figures 5A and 6A to be "Prior Art". Entry of the replacement sheets and withdrawal of the objection is requested.

The Examiner rejected claims 7, 8, 10, 15 and 17-20 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. US2003/0093042 to Leisner et al. ("Leisner"). Also under 35 U.S.C. 103(a), the Examiner rejected claims 14 and 16 as being unpatentable over Leisner in view of W002/00144 to Bager et al. ("Bager").

The present invention as set forth in claim 7 is directed to a body side wafer including a first part having a first surface adapted to be attached to or fixed to a body part of the person and a second, opposite surface; a second part having a first surface adapted to be attached to the ostomy bag

Serial No.: 10/577,054
Atty. Docket No.: P71223US0

and a second, opposite surface; and one or more welds formed at one or more welding zones between the second surfaces of the first part and the second part, at least one weld zone extending over a first distance in a radial direction. The first surface of the second part is at least substantially smooth at the at least one weld zone and over a second distance at least 1.5 times the first distance and extending radially over the at least one weld zone, *so that the first surface of the second part is suitable for adhesive attachment to the ostomy bag at the at least one weld zone and including at the site of the weld(s).* This is not shown by the prior art.

Leisner generally describes only the providing of a body side mounting wafer made of two elements attached to each other. In paragraphs [0026] and [0030], Leisner describes that these two elements may be attached to each other by welding (heat welding or UV welding) or by using an adhesive. The body side mounting wafer of Leisner is adapted to be fastened to a bag or pouch using an adhesive coupling of which one of the elements takes part.

It is essential that the adhesive coupling of the bag to the mounting wafer be both gas tight and liquid tight (in order to avoid embarrassing situations). This, in turn, puts

Serial No.: 10/577,054
Atty. Docket No.: P71223US0

demands on the smoothness of the surface that is to engage the adhesive, i.e. that surface of the body side mounting wafer which is opposite the side attached to the skin of the user.

From paragraphs [0027] and [0031] of Leisner, the skilled person is taught that when welding the two elements together, the thickness of the elements at the point of welding is preferably reduced in order to provide for improved heat transfer during the heat bonding process (see Figures 2a and 2b of Leisner). The heat bonding process is a standard heat welding, where heated surfaces contact the two elements from either side in order to provide heat that passes through the elements to the interface therebetween, in order for the adjacent portions of the two elements to fuse together.

Thus, the reduced thickness of the elements at the weld site is desired in order to facilitate the transfer of heat from the heated surfaces to the interface of the elements being welded. But while providing a benefit to the effectiveness of the heat welding, the reduced thickness produces a negative outcome in terms of the suitability of the resulting welded area for adhesive attachment. Specifically, by reducing the thickness at the point of the heat weld, the welded area of the flange or other welded element becomes useless for an adhesive coupling in

Serial No.: 10/577,054
Atty. Docket No.: P71223US0

that the abrupt thickness change creates a change in height with respect to the main upper surface of the element 100, making an effective adhesive coupling in this area impossible.

In addition, in order to transfer sufficient heat from the outer surfaces of the elements to the interface of such elements for the adjacent portions to melt, the material of the outer surfaces engaged will likewise melt and thus deform during heat welding. This is made worse in terms of deformation due to the fact that, to obtain a sufficiently high heat transfer to the interface, the heated surfaces engaging the outer surfaces of the elements to be welded compress and/or force the (molten) elements together, causing heat damage which further deforms the weld site as discussed in paragraph [0031] of Leisner. Hence, when two elements have been heat welded, it is not possible to use the surfaces close to the heat welds for the purpose of adhesive couplings.

The situation is the same for UV welding which is another welding type where heat is transferred from element outer surfaces to the interface between the elements (see page 1 of the present application). Thus, it is clear to the skilled person that to perform a heat or UV welding, the thickness of the

Serial No.: 10/577,054
Atty. Docket No.: P71223US0

elements at the weld site must be reduced and the welded surfaces will likely be deformed at least to some extent by heat damage.

As an alternative, Leisner teaches the use of adhesives (see paragraph [0026]). Adhesives do not require areas of reduced thickness (see Figures 2c-2f of Leisner) and do not cause deformation of the elements due to heat damage. However, the use of adhesives alone is generally not desirable for toxicological and environmental reasons (see page 1, lines 11-17, of the present application). Therefore, Leisner discloses the combination of heat welds between the base plate and the flange (see paragraphs [0027] and [0031]), and adhesive coupling between the flange and the bag (see paragraph [0026]).

Since Leisner presents a solution in which the base plate is fastened to the flange by heat welding, and then the bag is attached to the flange by adhesive, the skilled person would not look beyond Leisner. However, according to the configuration taught by Leisner, the welded area is not suitable for use in adhering the bag. On the contrary, the adhesive coupling as taught by Leisner must be made outside of the heat weld zones due to the uneven surfaces created by the heat welds. As shown in Figure 1 of Leisner, the weld is positioned at an inner periphery of the adhesive coupling area of the element 100. From Figure 1

Serial No.: 10/577,054
Atty. Docket No.: P71223US0

of Leisner, it is also clear that the inner opening in the flange 13 is larger than the outer periphery of the weld zone 205, so that the surface at the weld zone 205 is not used in the adhesive coupling. Because the weld zone cannot be used for adhesive coupling, it is necessary to increase the size of the flanges 13 and 11, as the flanges must provide respective area both for the adhesive coupling and the separate welded surface.

In the present invention as set forth in claim 7, and as contrasted with Leisner, welding and adhesives are combined while the welds are such that the surface at the weld itself is smooth and thus can also be used for the adhesive coupling to the bag. As a result, the position(s) of the weld(s) may be selected freely, as the welds do not ruin the suitability of the welded area for adhesive coupling. Through the claimed welding, the use of adhesives alone is avoided (which is desirable for toxicological and environmental reasons), and the need to enlarge the size of the flange or mounting wafer is also avoided.

In sum, according to the present invention, the smooth surface at the weld is larger than that of the weld, which means that *the surface at, and surrounding, the weld is smooth*. Thus, the surface at the weld is like that surrounding it (and which

Serial No.: 10/577,054
Atty. Docket No.: P71223US0

may have any size or area), so the surface at the weld itself may also take part in the adhesive coupling to the bag.

For at least the foregoing reasons, claim 7 is patentable over Leisner. Claims 8, 10 and 14-20 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter set forth therein.

Also, new claims 21 and 22 are allowable as they set forth parts especially adapted for laser welding in which the heat is transferred directly to the interface (due to the different absorption coefficients), so that welding at the interface is possible without melting/deformation of the parts at the outer surfaces thereof. Favorable consideration and allowance of claims 21 and 22 is requested.

As a final matter, the Examiner also rejected claims 7 and 16 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 7,244,482, and also provisionally rejected claims 7 and 16 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 34 of copending application Serial No. 11/578,366 and claim 36 of copending application Serial No. 11/826,266. Applicants request that further response in

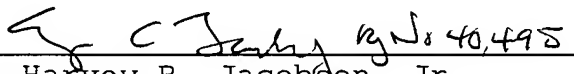
Serial No.: 10/577,054
Atty. Docket No.: P71223US0

connection with these issues be deferred pending the identification of allowable subject matter in the present application.

With this amendment and the foregoing remarks, it is respectfully submitted that claims 7, 8, 10 and 14-22 of the present application are in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By  40,495
for Harvey B. Jacobson, Jr.
Reg. No. 20,851

400 Seventh Street, NW
Washington, D.C. 20004-2201
Telephone: (202) 638-6666
Date: June 22, 2009
HBJ:SCB